2011 Current Fiscal Year Report: Secretary's Advisory Committee on Genetics, Health, and Society

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2011

3. Committee or Subcommittee	3b. GSA Committee No.
Secretary's Advisory Committee on Genetics, Health, and Society	13886

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	09/23/2010		

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
Yes	Departmental Determination	02/28/2011

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Terminate	No	

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42 USC 217a	11/17/1962	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
Reviewed revised draft report/discussionson of the final draft recommendations.	10/05/2010	- 10/06/2010

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$4,800.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$48,477.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$12,917.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00

18c. Other(rents,user charges, graphics, printing, mail, etc.)	$23,131.00	$0.00
18d. Total	$89,325.00	$0.00
19. Federal Staff Support Years (FTE)	0.30	0.00

20a. How does the Committee accomplish its purpose?

Advised and recommended on the range of complex and sensitive medical, ethical, legal, and social issues raised by new technological developments in human genetics. The Committee explored, analyzed, and deliberated on the broad range of human health and societal issues raised by the development and use, as well as potential misuse of genetic technologies and made recommendations to the Secretary of Health and Human Services.

20b. How does the Committee balance its membership?

The Committee consisted of up to 17 members, including the Chair, appointed by the Secretary from authorities knowledgeable about biomedical sciences, human genetics, health care delivery, evidence-based practice, public health, bioinformatics, behavioral sciences, social sciences, health services research, health policy, health disparities, ethics, economics, law, health care financing, consumer issues, and other relevant fields. Of the appointed members, at least two members were selected for their knowledge of consumer issues and concerns and the views and perspectives of the general public.

20c. How frequent and relevant are the Committee Meetings?

SACGHS held one meeting in FY 2011 before the expiration of its charter on February 28, 2011. At its October 2010 meeting, SACGHS discussed the revised draft report on genetics education and training and the revised draft recommendations, implications of affordable whole-genome sequencing, the implementation of the Genetic Information Nondiscrimination Act, the clinical utility and comparative effectiveness research of genetic tests, and perspectives on group risks and benefits of genomic data sharing. SACGHS also drafted a final letter to the Secretary recommending a specific course of action that HHS could take to further its understanding of genetic-related issues and develop policy solutions that address these issues.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The Committee provided a forum for expert discussion and deliberation and the formulation of advice and recommendations on the range of complex and sensitive medical, ethical, legal, and social issues raised by new technological developments in human genetics.

20e. Why is it necessary to close and/or partially closed committee meetings?
N/A

21. Remarks
This committee did not produce any reports during the reporting period. NIH and HHS have determined that the subject areas covered by this committee will be incorporated into other existing committees.

Designated Federal Officer
SARAH CARR EXECUTIVE SECRETARY

Committee Members	Start	End	Occupation	Member Designation
AMOS, MICHAEL	09/18/2006	02/28/2011	SCIENTIFIC ADVISOR	Ex Officio Member
ASPINALL, MARA	07/20/2007	02/28/2011	PRESIDENT AND CEO	Special Government Employee (SGE) Member
BACH, JANICE	05/26/2010	02/28/2011	STATE GENETICS COORDINATOR AND MANAGER	Special Government Employee (SGE) Member
BERRIEN, JACQUELINE	04/07/2010	02/28/2011	CHAIRMAN	Ex Officio Member
BILLINGS, PAUL	11/26/2008	02/28/2011	VICE PRESIDENT	Special Government Employee (SGE) Member
BORZI, PHYLLIS	12/01/2009	02/28/2011	ASSISTANT SECRETARY	Ex Officio Member
BOTHA, SARAH	01/20/2009	02/28/2011	ATTORNEY	Ex Officio Member
CAROME, MICHAEL	05/05/2003	02/28/2011	ASSOCIATE DIRECTOR FOR REGULATORY AFFAIRS	Ex Officio Member
DALE, DAVID	03/11/2009	02/28/2011	PROFESSOR OF MEDICINE	Special Government Employee (SGE) Member
DARIEN, GWEN	03/11/2009	02/28/2011	DIRECTOR, SURVIVOR AND PATIENT ADVOCACY	Special Government Employee (SGE) Member
DRELL, DANIEL	03/12/2004	02/28/2011	BIOLOGIST	Ex Officio Member
DREYFUSS, ROCHELLE	02/08/2008	02/28/2011	PAULINE NEWMAN PROFESSOR OF LAW	Special Government Employee (SGE) Member
ENG, CHARIS	05/28/2010	02/28/2011	CHAIR AND FOUNDING DIRECTOR	Special Government Employee (SGE) Member
EVANS, JAMES	09/30/2005	02/28/2011	ASSOCIATE PROFESSOR OF GENETICS & MEDICINE	Special Government Employee (SGE) Member
FERREIRA-GONZALEZ, ANDREA	06/28/2006	02/28/2011	PROFESSOR & DIRECTOR MOLECULAR DIAGNOSTICS LABORATORY	Special Government Employee (SGE) Member
FOX, ELLEN	03/01/2004	02/28/2011	DIRECTOR	Ex Officio Member
FROHBOESE, ROBINSUE	05/05/2003	02/28/2011	PRINCIPAL DEPUTY DIRECTOR	Ex Officio Member
GEOLOT, DENISE	08/01/2006	02/28/2011	DIRECTOR	Ex Officio Member
GOLDSTEIN, NAOMI	01/20/2009	02/28/2011	DIRECTOR, OFFICE OF PLANNING, RESEARCH AND EVALUATION	Ex Officio Member
GREEN, ERIC	12/01/2009	02/28/2011	DIRECTOR	Ex Officio Member
GUTIERREZ, ALBERTO	01/20/2009	02/28/2011	DEPUTY DIRECTOR, NEW PRODUCT EVALUATION	Ex Officio Member
KANIS, ADAM	05/12/2009	02/28/2011	LIEUTENANT COLONEL, MEDICAL CORPS. US ARMY CHIEF	Ex Officio Member
KHOURY, MUIN	05/05/2003	02/28/2011	DIRECTOR	Ex Officio Member
MCGRATH, BARBARA	06/28/2006	02/28/2011	RESEARCH ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
NUSSBAUM, SAMUEL	04/13/2010	02/28/2011	EXECUTIVE VICE PRESIDENT	Special Government Employee (SGE) Member

RANDHAWA, GURVANEET	08/01/2006	02/28/2011	SENIOR FELLOW	Ex Officio Member
ROYAL, CHARMAINE	03/11/2009	02/28/2011	ASSOCIATE RESEARCH PROFESSOR	Special Government Employee (SGE) Member
STRAUBE, BARRY	08/01/2006	02/28/2011	CHIEF MEDICAL OFFICER	Special Government Employee (SGE) Member
TEUTSCH, STEVEN	06/28/2006	02/28/2011	CHIEF	Special Government Employee (SGE) Member
WALCOFF, SHEILA	03/11/2009	02/28/2011	PARTNER	Special Government Employee (SGE) Member
WILLIAMS, MARC	03/27/2007	02/28/2011	DIRECTOR OF THE CLINICAL GENETICS INSTITUTE	Special Government Employee (SGE) Member
WISE, PAUL	05/06/2008	02/28/2011	RICHARD E. BEHRMAN PROFESSOR OF CHILD HEALTH & SOCIETY	Special Government Employee (SGE) Member

Number of Committee Members Listed: 32

Narrative Description

In FY 2011, the Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) completed its work on behalf of the Secretary of Health and Human Services (HHS). Its mandate related to the HHS mission of enhancing the health and well-being of Americans and, more specifically, to HHS strategic goals of improving the safety, quality, affordability and accessibility of health care and advancing scientific and biomedical research and development related to health.SACGHS explored, analyzed, and deliberated on the broad range of policy needs associated with the scientific, clinical, public health, ethical, economic, legal and social issues raised by the development, use, and potential misuse of genetic and genomic technologies and made recommendations to the HHS Secretary and others upon request. The following topics were SACGHS priorities: the clinical utility of genetic and genomic technologies; consumer-initiated genomic services; coverage and reimbursement of genetic tests and services; genetics education and training; genetics and the future of the health care system; informed consent, privacy, and discrimination related to genomic data sharing; and public health genomics. Health disparities were considered across all of the other priority topics, and genetic discrimination, oversight of genetic testing, and gene patents and licensing were of ongoing interest.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	

Increased customer satisfaction	☐
Implementation of laws or regulatory requirements	☐
Other	☐

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	☑
Unable to Determine	☐
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

NIH supported basic and clinical research accomplishments often take many years to unfold into new diagnostic tests and new ways to treat and prevent diseases.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

90

Number of Recommendations Comments

In recommendations made in October 2010, SACGHS identified salient concerns in genomic data sharing, implications of affordable whole-genome sequencing, comparative effectiveness research in genomic and personalized medicine, and public health implications of genomics. The Committee also made seven recommendations that proposed steps that could be taken by HHS to develop policy solutions addressing those concerns. The Committee also provided a set of principles to guide the integration of genetics and genomics in clinical care and public health as new issues arise. In February 2011, SACGHS submitted to the Secretary the report Genetics Education and Training identifying needs in genetics education and training for point-of-care health professionals, the public health workforce, and patients and consumers and making six recommendations to address those needs.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
0%

% of Recommendations Fully Implemented Comments
Due to the large breadth and complexity of the recommendations made by this committee to the Secretary, NIH/OD staff is unable to determine which recommendations have been fully implemented solely in response to this committee's activities. Additionally, since this committee was terminated on February 28, 2011, the final recommendations by the committee were forwarded to the Secretary and we are waiting to hear a determination on what recommendations will be accepted.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
21%

% of Recommendations Partially Implemented Comments
Recommendations implemented: Recommendation from the 2008 SACGHS report U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services that called for HHS to develop and maintain a mandatory registry for laboratory tests. On March 18, 2010, the National Institutes of Health (NIH) announced that it plans to develop a voluntary registry for genetic tests (http://www.nih.gov/news/health/mar2010/od-18.htm).Recommendation from the 2008 SACGHS report U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services that called for HHS to ensure the coordination and implementation of efforts to advance the appropriate use of interoperable patient-level data for research and enhance the quality of decisionmaking. The criteria for the meaningful use of electronic health records (EHRs)—developed by the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services—support the use of EHRs to advance research (http://edocket.access.gpo.gov/2010/E9-31216.htm).Recommendation from the 2008 SACGHS report U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services that called for resources to translate genetic and genomic research into evidence-based clinical practice guidelines that enhance the quality of clinical health care and public health care outcomes. The Centers for Disease Control and Prevention has initiated the Genomic Applications in Practice and Prevention Network (GAPPNet™) to accelerate and streamline the effective and responsible use of validated and useful genomic knowledge and applications, such as

genetic tests, technologies, and family history, into clinical and public health practice (http://www.cdc.gov/genomics/translation/GAPPNet/). Recommendation from the 2007 SACGHS report Policy Issues Associated with Undertaking a New Large U.S. Population Cohort Study of Genes, Environment, and Disease that called for the HHS Secretary to assess the public's willingness to participate in a large population cohort study in advance of any funding decision. NIH funded studies to assess public opinions and expectations of a large genetic cohort study. Two papers were published reporting results of these studies: Kaufman D, Murphy J, Scott J, Hudson K. Subjects matter: a survey of public opinions about a large genetic cohort study. Genetics in Medicine. 2008 Nov;10(11):831-9.Murphy J, Scott J, Kaufman D, Geller G, LeRoy L, Hudson K. Public expectations for return of results from large-cohort genetic research. American Journal of Bioethics. 2008 Nov;8(11):36-43.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

DHHS provided feedback in writing and orally through the HHS ex officios serving on SACGHS about its plans to implement the Committee's recommendations. Key staff in the Secretary's immediate office provided updates on the status of the Committee's recommendations as well as information about Secretarial programs and priorities. Staff level discussions also provided feedback on the work of the Committee and helped identify additional areas in which the Committee could work synergistically with the Department.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☐
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

A number of SACGHS recommendations are being considered by HHS agencies and action is underway to address some recommendations. For example, the Centers for

Medicare & Medicaid (CMS) is working with the Clinical Laboratory Improvement Advisory Committee towards the development of a notice for proposed rulemaking to update requirements for proficiency testing, which would address one of the recommendations in the SACGHS report on the oversight of genetic testing. The proposed rule is expected in 2011. CMS has also worked with its Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) to examine whether the use of genetic tests can improve health outcomes for the Medicare population. In 2009 and 2010, MEDCAC held three meetings that focused on diagnostic genetic tests, genetic tests used for screening purposes, and pharmacogenomic tests to inform cancer treatments. MEDCAC examined issues pertinent to recommendations in SACGHS reports on pharmacogenomics and the coverage and reimbursement of genetic tests and services. The SACGHS report on the oversight of genetic testing recommended that the Food and Drug Administration (FDA) apply its risk-based regulatory approach to laboratory-developed tests (LDTs). FDA held a meeting July 19-20, 2010, to gather public input on an oversight framework for LDTs that encourage innovation and improve patient outcomes. The Federal Register notice announcing this meeting cited the SACGHS recommendation. In March 2011, the FDA held a public meeting on direct-to-consumer (DTC) genetic testing. One of the meeting agenda items—regarding the level and type of scientific evidence appropriate for supporting DTC genetic testing claims—addressed the Committee's concern about the absence of FDA review of claims and promotional materials for DTC genetic tests, which was raised in the 2010 SACGHS report on this topic.The SACGHS oversight report also recommended that HHS identify and address deficiencies in knowledge about appropriate genetic and genomic test applications in practice and educate key groups such as health care practitioners. Consistent with this recommendation, the Agency for Healthcare Research and Quality (AHRQ) held a workshop in February 2010 to examine issues that primary care clinicians face in using genetic and genomic tests. To complement this workshop, AHRQ produced a draft white paper on the primary care perspective on the appropriate use of genomics. AHRQ's efforts have identified deficiencies in the knowledge base and potential remedies that would assist primary care clinicians in the appropriate use of gene-based tests.In May 2010, AHRQ issued the technology assessment (TA) Quality, Regulation and Clinical Utility of Laboratory-developed Molecular Tests. This TA examined several issues raised in the SACGHS reports on the oversight of genetic testing and DTC genetic testing, such as inadequate data to assess the clinical utility of tests, insufficient analysis of the standard of evidence on which clinical utility should be evaluated, and inadequate regulation of marketing claims. Under development is an AHRQ report on analytic validity, quality rating, and evaluation frameworks of genetic and other laboratory tests. The AHRQ report examines concerns raised in SACGHS oversight report on gaps in the extent to which analytic validity data can be generated and evaluated for genetic tests.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

NIH website: http://oba.od.nih.gov/SACGHS/sacghs_home.htmlThis committee's information is listed here such as the committee charter, minutes, agenda and future meeting dates.